Canadian Journal of Cardiology 30 (2014) 1245–1248

Training/Practice
Training/Health Policy and Promotion

Aligning Health Care Policy With Evidence-Based Medicine: The Case for Funding Direct Oral Anticoagulants in Atrial Fibrillation

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ABSTRACT

Misalignment between evidence-informed clinical care guideline recommendations and reimbursement policy has created care gaps that lead to suboptimal outcomes for patients denied access to guideline-based therapies. The purpose of this article is to make the case for addressing this growing access barrier to optimal care. Stroke prevention in atrial fibrillation (AF) is discussed as an example. Stroke is an extremely costly disease, imposing a significant human, societal, and economic burden. Stroke in the setting of AF carries an 80% probability of death or disability. Although two-thirds of these strokes

RÉSUMÉ

Le manque de concordance entre les recommandations formulées dans les lignes directrices des soins cliniques fondées sur des données probantes et les politiques de remboursement a créé des lacunes en matière de soins qui entraînent des résultats sous-optimaux chez les patients dont l'accès aux traitements basés sur les lignes directrices est refusé. Le but de cet article est de faire en sorte que ces obstacles à l'accès aux soins optimaux qui se font de plus en plus nombreux soient surmontés. À titre d'exemple, nous traitons de la prévention de l'accident vasculaire cérébral (AVC) associée à la fibrillation auriculaire

Given recent economic circumstances, government payers feel obliged to contain the rate of growth of public expenditures. Cost and legal concerns tend to take precedence over scientific considerations in bureaucratic policy decisions,[1] resulting in misalignment between evidence-informed clinical care guideline recommendations and reimbursement policy. Care gaps are created when health care providers are unable to consistently offer guideline-based therapies and this might lead to suboptimal outcomes for patients denied access to these therapies.

Lack of harmonization between reimbursement policy and evidence-informed clinical care guideline recommendations represents an increasing obstacle for the translation of knowledge and its application in the clinical setting. The purpose of this article is to make the case for addressing this growing access barrier to optimal care. Opportunities for improving stroke prevention in atrial fibrillation (AF) are discussed as an example.

Received for publication June 6, 2014. Accepted August 7, 2014.

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See page 1248 for disclosure information.

http://dx.doi.org/10.1016/j.cjca.2014.08.002

are preventable with appropriate anticoagulation, this has historically been underprescribed and poorly managed. National and international guidelines endorse the direct oral anticoagulants as first-line therapy for this indication. However, no Canadian province has provided these agents with an unrestricted listing. These decisions appear to be founded on silo-based cost assessment—the drug costs rather than the total system costs—and thus overlook several important cost-drivers in stroke. The discordance between best scientific evidence and public policy requires health care providers to use a potentially suboptimal therapy in contravention of guideline recommendations. It represents a significant obstacle for knowledge translation efforts that aim to increase the appropriate anticoagulation of Canadians with AF. As health care professionals, we have a responsibility to our patients to engage with policy-makers in addressing and resolving this barrier to optimal patient care.

(FA). L'AVC est une maladie qui coûte très cher et qui impose par conséquent un fardeau humain, social et économique important. L'AVC qui survient dans le cadre de la fibrillation auriculaire induit une probabilité de mortalité ou d'incapacité estimée à 80 %. Bien que les deux tiers de ces AVC puissent être évités par une anticoagulation appropriée, ils ont traditionnellement fait l'objet d'une prescription sous-optimale et d'une prise en charge médiocre. Les lignes directrices nationales et internationales soutiennent que les anticoagulants oraux directs comme traitement de première intention sont indiqués. Cependant, aucune province canadienne n'a fourni une liste non restrictive de ces agents. Ces décisions semblent fondées sur l'évaluation des coûts directs (les coûts des médicaments plutôt que les coûts totaux du système) et, par conséquent, omettent plusieurs inducteurs importants de coûts liés à l'AVC. La discordance entre les meilleures données scientifiques et les politiques publiques oblige les fournisseurs de soins de santé à utiliser un traitement potentiellement sous-optimal en ne tenant pas compte des recommandations formulées dans les lignes directrices. Il représente un obstacle important aux efforts de transmission des connaissances qui visent à accroître l'utilisation de l'anticoagulation appropriée chez les Canadiens souffrant de FA. Comme professionnels de la santé, nous avons la responsabilité envers nos patients de collaborer avec les responsables de l'élaboration des politiques pour surmonter et résoudre ces obstacles qui empêchent les patients d'avoir accès aux soins optimaux.

The Cost of Cost-Containment

Stroke is an extremely costly disease, imposing a significant human, societal, and economic burden. It strikes frequently, often resulting in death or significant disability, with profound effects on individual quality of life and the functioning of families and social networks.

Stroke and dementia are responsible for some of the longest lengths of stay in Canadian hospitals. A recent Canadian stroke-costing study reported the average overall cost of the first year of stroke as $74,353.[2] The initial 3 months accounted for 54.5% of the overall costs and were driven primarily by hospitalization and rehabilitation. Subsequently, indirect costs such as rehabilitation, home care, and paid caregivers represented the bulk of expenditures. Although more difficult to quantify than direct costs such as drugs and acute hospitalization, and thus seldom considered in policy decision-making, these latter costs contribute substantially to the overall societal cost of stroke.

AF affects upwards of 1 in 10 people older than age 75 years and increases the risk of stroke fivefold. Stroke in the setting of AF carries an 80% probability of death or disability. Two-thirds of these strokes are preventable with appropriate anticoagulation, but this has historically been underprescribed and poorly managed despite considerable effort, with resultant significant care gaps for the Canadian population with AF.

National guidelines endorse the direct oral anticoagulants (dabigatran, rivaroxaban, and apixaban) as being preferred to warfarin for stroke prevention and reducing the risk of intracranial bleeding, and hence the first line therapy for this indication.[3] The Canadian Agency for Drugs and Therapeutics in Health (CADTH) has recommended that these agents receive reimbursement only if warfarin cannot be used (eg, because of allergy) or after an initial attempt with warfarin therapy has been unsuccessful (www.cadth.ca/en/products/cadth-overviews/overview-volume-3/3-2-02). Provincial payers have uniformly adopted CADTH's recommendations in their reimbursement guidelines; see Supplemental Table S1.

This discordance between evidence and public policy places health care providers in an awkward position. They are required to treat many patients in a manner that is at variance with national guidelines and this might have a deleterious clinical effect in light of recent evidence of heightened risk of both ischemic stroke and bleeding in the first month of initiating warfarin therapy (Supplemental Table S2). Some patients will be able to access the preferred direct anticoagulants if they have separate third-party coverage or are willing to pay. But this effectively results in a 2-tiered level of care with better stroke prevention for these individuals compared with others who do not have supplemental coverage and are not fiscally able to absorb the costs.

Removal of funding restrictions for evidence-based therapies can be expected to increase utilization of these therapies and thereby result in improved outcomes. Indeed, this has been demonstrated in an Institute for Clinical Evaluative Sciences study of cardiovascular outcomes after a change in the prescription policy for clopidogrel.[4] Removing the requirement for previous authorization led to more timely access to therapy and improved cardiovascular outcomes in patients who required coronary stenting.

Harmonization between policy and evidence is an essential and achievable goal. Acute stroke thrombolysis is a prime example of how a therapy with a high unit cost can nevertheless have significant clinical and health system benefit, including generalized cost-effectiveness through reducing hospital and rehabilitation costs. Through collaboration between multiple specialties, support services, and government agencies, trial results were translated into standardized systems of care such as emergency room bypass protocols and hospital

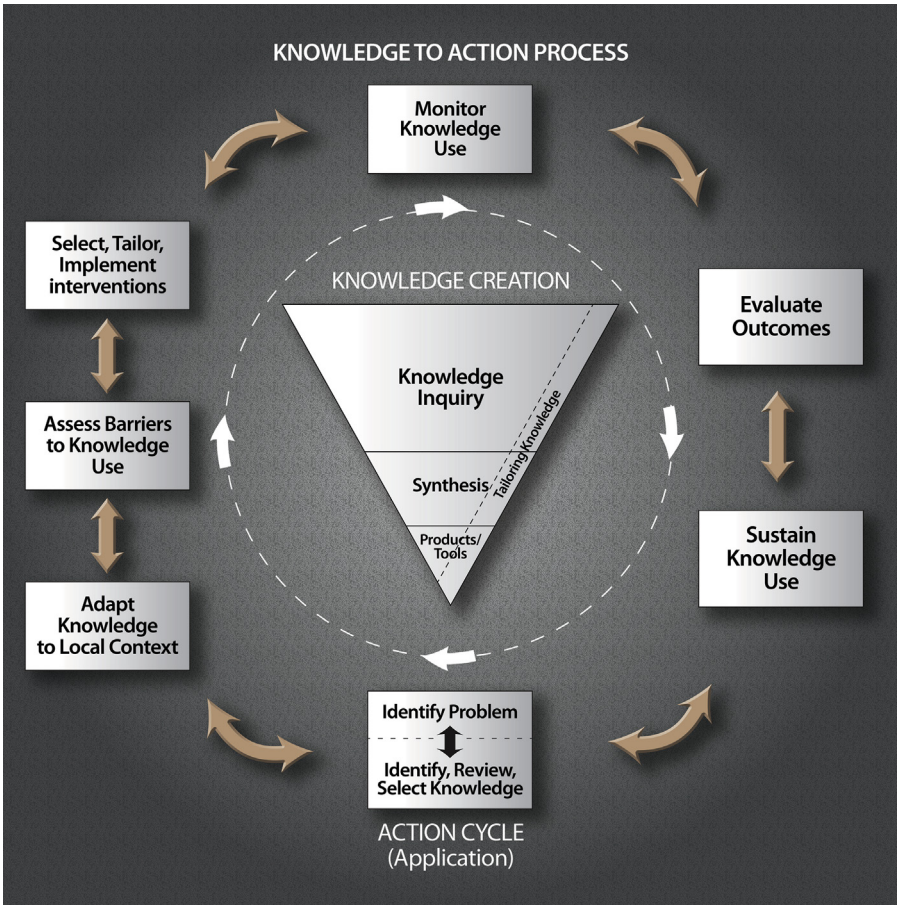

Figure 1. Canadian Institutes of Health Research knowledge to action process. Reproduced from Canadian Institutes of Health Research (http://www.cihr-irsc.gc.ca/e/39033.html#Knowledge-Users).

stroke teams. Stroke best practice guidelines were developed and promulgated. Ministries of Health established policies and set reimbursement and fee schedules to support implementation. This process of knowledge translation at multiple levels has led to Canada boasting some of the highest rates of acute stroke treatment in the world, being approximately 4 times higher than that in the United States.

There Is a Better Way: A Call to Action

Knowledge translation initiatives have been implemented across Canada that encourage all health care professionals to collaboratively implement clinical care protocols for individuals with AF that are derived from evidence-informed guidelines. The Canadian Institutes of Health Research has developed a "Knowledge to Action Process" (Fig. 1) that describes the relationship between the creation of knowledge and its application (www.cihr-irsc.gc.ca/e/39033.html#Knowledge-Users). The "action cycle" around the central knowledge creation funnel represents activities needed for knowledge to be applied. Assessment of barriers is an element of this cycle that is particularly relevant to this discussion. Barriers can relate to lack of knowledge regarding appropriate management or be obstacles within the system of care. We believe that misalignment between reimbursement policy and national clinical care guidelines regarding stroke prevention in AF is a system-based obstacle that is a priority to address. Despite a strong base of scientific knowledge that serves as the foundation for clinical guidelines, this lack of harmonization presents a significant obstacle to the success of knowledge translation activities.

It must be acknowledged that cost is not addressed in evidence-based guidelines; in Canada, this has been a role assumed by CADTH. In this example, CADTH appears to have considered only direct costs (eg, drug acquisition, cost of international normalized ratio management itself, treatment costs for bleeding, and avoidable stroke) in its evaluation. A more global assessment that includes opportunity costs (cost of the outcome to the patient) and indirect costs (eg, costs associated with undergoing international normalized ratio assessment, lost productivity due to stroke, and longer-term expenses of caring for individuals who have experienced stroke) would seem more appropriate in this setting because these costs are often significant. Comprehensive cost effectiveness analyses of the direct oral anticoagulants have been published[5]; these analyses can provide valuable information to assist policy-makers and, whenever available, should be taken into account in funding decisions.

In its CanMEDS Physician Competency Framework, the Royal College of Physicians and Surgeons of Canada lists 7 roles required of physicians, 1 of which is "health advocate" (www.royalcollege.ca/portal/page/portal/rc/canmeds/framework).

The College states that "…health advocacy involves efforts to change specific practices or polices on behalf of those served… Health advocacy is appropriately expressed both by individual and collective actions of physicians in influencing public health and policy." Indeed, health advocacy is a responsibility also shared by other health care providers. The physician's role of "Manager" in CanMEDS is also noted; a key competency associated with this role is to "allocate finite health care resources appropriately" by balancing effectiveness, efficiency, and access with optimal care and by applying evidence and management processes for cost-appropriate care.

The possibility of conflict between these 2 roles is recognized in the CanMEDS Framework. However, we believe that engaging with policy-makers to replace the silo-based cost assessments currently used in policy decision-making with system-based cost assessments is, in fact, necessary to effectively fulfil both roles.

Conclusions

As the population ages, the absolute number of Canadians with AF will increase, resulting in an increased demand on health services. In Canada, health care expenditures are the single largest category of public expenses with a growth rate that overshadows the rate of economic growth. System sustainability is indeed threatened; but collapse is not inevitable. It is within our personal and professional capacity to direct our efforts at prevention of diseases such as stroke that have such significant human and economic consequences. Appropriate anticoagulation of individuals with AF is an extremely effective means of accomplishing this.

Although knowledge translation efforts to address this need and improve patient care are ongoing, misalignment between evidence-informed guidelines and reimbursement policy represents a significant obstacle. Removing this barrier to successful knowledge translation would contribute greatly to reducing AF-related stroke.

We all have a role to play in system sustainability and patient accountability. As health care professionals, it is our responsibility to interpret the best available evidence and collaborate with policy-makers in applying the evidence to formulate health policy. We must remember that we are here to serve our patients. Cost containment is essential. However, we must ensure that we consider a complete assessment of costs when we make policy decisions and not limit the scope to select budget silos. Silo-based cost assessments serve no one well—not patients, and not society. Furthermore, unilaterally allowing cost considerations to trump the recommendations of evidence-informed clinical practice guidelines forces health care providers into an ethically untenable clinical practice environment in which they are required to prescribe therapies they know to be subordinate to the scientifically validated alternatives.

Finally, we must be diligent in fulfilling our responsibility to patients to the best of our abilities. As health care professionals, we can individually and collectively advocate for enlightened public health and policy to improve the overall health and well-being of Canadians—indeed, we have an obligation to do so.

Funding Sources

Boehringer Ingelheim Canada Ltd sponsored a half-day meeting attended by the authors that led to the development of this report. Boehringer Ingelheim was neither represented at meetings and teleconferences, nor provided any input into the writing or editing of the article.

Disclosures

See the *Disclosures* section of the Supplementary Material.

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at http://dx.doi.org/10.1016/j.cjca.2014.08.002.